Optimalisation of the response to influenza virus vaccination in breast cancer and colorectal cancer patients immunocompromised due to chemotherapy.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20352

Source
NTR

Brief title
OFLUVAC

Health condition

Vaccination, Influenza, Chemotherapy, breast cancer, colorectal cancer

Sponsors and support

Primary sponsor: University Medical Center
Source(s) of monetary or material Support: University Medical Center

Intervention

Outcome measures

Primary outcome

Adequate rise in antibody titre.

Secondary outcome

1. Antibody titres against the influenza virus before and after vaccination;

2. Ex vivo cellular immune response (cytokines, fine specificity) after vaccination.

Study description

Background summary

Background:

Patients treated with chemotherapy are at higher risk of influenza infection and mortality and morbidity are higher compared to healthy adults. Vaccination against the influenza virus can prevent these complications. Although vaccination in oncology patients is recommended, in the Netherlands, a protocol for vaccination during chemotherapy does not exist. In this study it is investigated whether vaccination
during chemotherapy is effective in reaching protective serum antibody concentrations and adequate cellular immune response. Moreover the timing of vaccination is investigated (early vs late vaccination).

Objective:

To evaluate the effect of chemotherapy on the serological and cellular immune response to influenza virus vaccination in patients with breast or colorectal cancer in order to establisch the optimal timing of vaccination during treatment with chemotherapy.

Study design:

Randomized Clinical Trial (Multicentre).

Study population:

1. Patients with breast cancer, treated with FEC- or TAC-containing, triweekly chemotherapy cycles at the time of influenza vaccination;

2. Patients with colorectal cancer, treated with Oxaliplatin-containing, triweekly chemotherapy cycles at the time of vaccination;

3. Healthy controls consisting of patients partners and healthy volunteers working in the hospital.

Intervention:

The influenza virus vaccine is given in the period October/November 2011.

Main studyparameters/endpoints:

Adequate rise in antibody titre.

Study objective

Patients treated with chemotherapy are at higher risk of influenza infection and mortality and morbidity are higher compared to healthy adults. Vaccination against the influenza virus can prevent these complications. Although vaccination in oncology patients is recommended, in the Netherlands, a protocol for vaccination during chemotherapy does not exist. In this study it is investigated whether vaccination
during chemotherapy is effective in reaching protective serum antibody concentrations and adequate cellular immune response. Moreover the timing of vaccination is investigated (early vs late vaccination).

Study design

Aim: Inclusion finalized by december 2011.

Intervention

The influenza virus vaccine is given in the period October/November 2011.

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

1. Patients with breast cancer treated FEC- or TAC-containing triweekly chemotherapy at moment of vaccination;

2. Patients with colorectal cancer treated with Oxaliplatin-containing triweekly chemotherapy at moment of vaccination;

3. Age >18 years;

4. Signing informed consent;

5. Male and Female.

Exclusion criteria

1. Fever at time of vaccination defined as a temperature of > 38.5 C;

2. Previous/known allergic reaction to any of the components of the vaccines given, for example hypersensitivity to egg protein;

3. Thrombocytopenia (defined as < 50 * 109/L) at moment of vaccination.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	180
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2720
NTR-old	NTR2858
Other	EudraCT number : 2011-001714-34
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A